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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,146	01/02/2001	Rolando Barbucci	515-4204	8284
47888	7590	12/15/2004		
HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036				
			EXAMINER SERGEANT, RABON A	
			ART UNIT 1711	PAPER NUMBER

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,146

Applicant(s)

BARBUCCI ET AL.

Examiner

Rabon Sergent

Art Unit

1711

[Handwritten signature]

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-21,23-34,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-21,23-34,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 2, 4, 5, 13-16, 19, 21, are 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' amendment of September 23, 2004 has introduced several errors into the claims. The following errors have been noted. Claims 2 and 4 have been amended to depend on Claim I. Within claim 4, the A2) component has been amended and is unintelligible. Claim 13 has been amended to refer to a natural~synthetic polymer; however, it is unclear what is meant by the terminology. Claim 21 has been amended to refer to 4,41-methylenebis (phenyl isocyanate). Claim 23 has been amended to refer to any of claim 20.

2. Claims 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants have failed to specify the type of molecular weight (i.e.; number average or weight average).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 4-21, 23-34, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs et al. ('865) in view of WO 95/25751 and Halpern et al. ('114).

Balazs et al. disclose the covalent bonding of hyaluronic acid to polyurethane and the use of such materials in medical applications. See example 3.

5. Balazs et al. are silent regarding the sulphate modification of the hyaluronic acid component; however, sulphated hyaluronic acids and their use with polyurethanes and within medical applications was known in the art at the time of invention. This position is supported by the teachings of WO 95/25751. See entire document and especially line 20 of page 28.

Furthermore, the covalent bonding of polysaccharides, including sulphate containing polysaccharides, to substrates, including isocyanate group containing substrates, to produce medical articles was known at the time of invention. See abstract; figures; and column 4, lines 20+ within Halpern et al.

6. In view of the teachings within Halpern et al. regarding the bonding of sulphate polysaccharides to isocyanate containing substrates, the position is taken that it would have been obvious to utilize the sulphated hyaluronic acids of WO 95/25751 as the hyaluronic acid component of Balazs et al., so as to arrive at the instant invention.

7. The examiner has considered applicants' arguments; however, it is by no means clear that applicants' claiming of a compound distinguishes the instant claims from the prior art.

Furthermore, it is not seen that the argument addresses the issue of obviousness set forth by the

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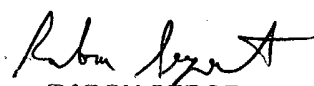
examiner. Regardless of whether a reaction is occurring in bulk or on the surface, it would seem that the same chemistry is at work, and it is not seen that applicants' remarks have clearly addressed this issue. Despite applicants' remarks, the teachings of the references are considered to render obvious the covalent bonding of sulphated hyaluronic acid derivatives to polyurethane. However, it is requested that applicants elaborate on their remarks concerning Example 11 at page 17 of the specification.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (571) 272-1079.

R. Sergent
December 13, 2004


RABON SERGENT
PRIMARY EXAMINER